

### REMARKS

This is in response to the Office Action of February 24, 2009. Claims 1-18 are pending in the present application. Claims 1, 7 and 13 are independent.

In the Office Action, the Examiner: (1) rejected claims 1, 2, 4, 5, 7, 10 and 11 under 35 USC 103 as being unpatentable over US 5,350,357 to Kamen et al. in view of US 4,750,868 to Lundback and (2) rejected claims 2, 3, 6, 8, 9 and 12-18 under 35 USC 103 as being unpatentable over Kamen in view of Lundback and further in view of US 5,954,971 to Pages.

At the outset, Applicants note that in the Office Action (page 2), the Office cites US Patent No. 4,647,877 as the Lundback reference, but Applicants believe this to be a typographical error. Applicants assume that the Office intended to cite US Patent No. 4,750,868 to Lundback, as shown in the attached Notice of References Cited.

Applicants also wish to thank the Examiner for considering the references submitted in the Supplemental Information Disclosure Statement on November 18, 2008.

#### Claims 1, 2, 4, 5, 7, 10 and 11 Would Not Have Been Obvious over US 5,350,357 to Kamen et al. in view of US 4,750,868 to Lundback

In response to the rejection of claims 1, 2, 4, 5, 7, 10 and 11 under 35 USC § 103, and without acquiescing in the rejection, Applicants have amended independent claims 1 and 7 to further define the claimed subject matter. In particular, claims 1 and 7 have been amended to recite that during the first flow mode and second flow mode, the

pump strokes draw a blood volume for a first duration into the blood inlet of the respective first and second pump stations and expel a blood volume for a second duration from the blood outlet of the respective first and second pump stations, wherein the first duration is longer than the second duration. A control function operates to synchronize the pump strokes so that fluid (blood) flow from the source is essentially continuous while fluid (blood) flow to the destination is pulsatile.<sup>1</sup> In contrast, the cited references do not, either alone or in combination, describe or suggest a fluid (or blood) processing system as presently claimed, as set forth below.

First, it is respectfully submitted that the Kamen patent does not disclose (1) pump strokes that draw a blood volume for a first duration into a blood inlet of a respective first and second pump station and expel a blood volume for a second duration from a blood outlet of a respective first and second pump station, and (2) wherein the first duration is longer than the second duration.

Instead, Kamen generally describes a dialysis system in which a controller works pump chamber P2 in tandem with pump chamber P1. Specifically, a controller works pump chamber P1 in a draw stroke, while working pump chamber P2 in a pump stroke, and vice versa. In this sequence, heated dialysate is always introduced into the top portions of pump chambers P1 and P2 and always discharged through the bottom portions of pump chambers P1 and P2. See Kamen col. 31, line 62 through col. 32 line 10. In other words, Kamen describes tandem pumping of P1 and P2 where one pump

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<sup>1</sup> Applicants submit that the amendments to the claims are fully supported by the application specification as originally filed and do not add new matter. See, for example, paragraphs [0482]-[0483] of the published application.

draws while the other pumps, in succession, to achieve continuous fluid outflow.

However, Kamen does not describe, contemplate or suggest pump strokes that draw a fluid volume for a first duration and expel a fluid volume for a second duration and where the first duration is longer than the second duration – and there is no logical rationale or basis that a skilled person would use to reach the claimed invention. The objective in Kamen is to obtain continuous flow, not discontinuous flow.

Accordingly, amended independent claims 1 and 7 and the respective dependent claims would not have been obvious over Kamen. Further, Lundback does not describe any of the subject matter missing from Kamen. Thus, even if one were to make the unlikely combination of the dialysis system disclosed in Kamen with the pump described in Lundback, the result would still not have the features of the claimed fluid processing system of claim 1 (or blood processing system as recited in claim 7).

Specifically, the Lundback patent does not disclose pump strokes that draw a blood volume for a first duration into a blood inlet of a respective first and second pump station and expel a blood volume for a second duration from a blood outlet of a respective first and second pump station, wherein the first duration is longer than the second duration as presently claimed. Further, Lundback also does not disclose other features of the claimed system as recited in independent claims 1 and 7, including (1) first and second fluid pressure actuated pump stations each comprising a separate fluid inlet and a separate fluid outlet, and (2) a fluid pressure actuator operating to selectively apply fluid pressure pump strokes in tandem to first and second pump stations, the fluid pressure actuator including a control function to switch between a first flow mode and a

second flow mode. It is therefore respectfully submitted that it would not have been obvious to one skilled in the art to combine Kamen with the pump of Lundback to reach the present invention, as described in further detail below.

Instead, Lundback describes generally only a *single* pump having a *single* inlet and a *single* outlet that can be used in industry, mining, and the like. In the Office Action, it appears that the Office considers pump chambers "A" and "V" of Lundback to be comparable to the claimed "first and second fluid pressure actuated pump stations". However, pump chambers "A" and "V" of Lundback communicate with only one inlet and one outlet—that is, there is a single inlet and a single outlet through which fluid enters and exits the Lundback pump. Thus, Lundback does not describe or even contemplate first and second fluid pressure actuated pump stations that each comprise a separate fluid inlet and a separate fluid outlet as required by amended claims 1 and 7. The Lundback structure is so physically different from that of Kamen and operates in such a fundamentally different way, that the idea of combining them to get the claimed combination is, from an engineering standpoint, not seemingly practical or possible.

Further, Lundback also does not describe a fluid pressure actuator operating to selectively apply fluid pressure pump strokes in tandem to first and second pump stations, the fluid pressure actuator including a control function to switch between a first flow mode and a second flow mode. Instead, as already described above, the so-called pump chambers "A" and "V" of Lundback communicate with only one inlet and one outlet. There is no description of a fluid pressure actuator operating to selectively apply fluid pressure pump strokes in tandem to first and second pump stations wherein each

of the first and second pump stations comprises a separate fluid inlet and a separate fluid outlet as presently claimed, and further, no matter how the Lundback pump is operated it would not be capable of switching between a first and second flow mode in which pump strokes draw a fluid (or blood) volume into separate fluid inlets of first and second pump stations and expel fluid (or blood) from separate fluid outlets of first and second pump stations, respectively, as set forth in amended independent claims 1 and 7.

Finally, Lundback does not describe pump strokes that draw a fluid (or blood) volume for a first duration into a fluid (or blood) inlet of a respective first and second pump station and expel a fluid (blood) volume for a second duration from a fluid (blood) outlet of a respective first and second pump station, wherein the first duration is longer than the second duration as presently claimed. Instead, Lundback generally describes a “self regulating” pump where the degree of filling chamber V is dependent on the pressure of the incoming pumped medium which thereby also controls the capacity of the pump at any given constant stroke rate. See Lundback, col. 5, line 68 through col. 6, line 4. Thus, while pump chamber A is drawing fluid, pump chamber V is simultaneously expelling fluid. See col. 1, lines 64-68 and col. 5, lines 37-44. Lundback, however, does not disclose or contemplate pump strokes that draw a fluid (or blood) volume for a first duration and a expel a fluid (blood) volume for a second duration from respective first and second pump stations, wherein the first duration is longer than the second duration as presently claimed. The Lundback “pump” is a

completely different idea from an engineering perspective and the suggested combination just doesn't make logical sense to the undersigned.

Therefore, it is submitted that it would not have been obvious to one skilled in the art to combine the features of the dialysis system described in Kamen with the pump described in Lundback to reach the present invention. For at least these reasons, amended independent claims 1 and 7 and the respective dependent claims 2, 4, 5, 10 and 11 would not have been obvious over Kamen, either alone or in combination with Lundback.

Independent Claim 13 and Dependent Claims 2, 3, 6, 8, 9, 12 and 14-18 Would Not Have Been Obvious Over Kamen in View of Lundback, and Further in View of US 5,954,971 to Pages

Applicants respectfully submit that amended independent claim 13 and the dependent claims identified above also would not have been obvious in view of the cited references. In particular, independent claim 13 has been amended, like claims 1 and 7, to further distinguish the cited references and requires, among other things, pump strokes that draw a blood volume for a first duration into the blood inlet of the first pump station from the source and expel a blood volume for a second duration from the blood outlet of the second pump station to the filter, and a second flow mode, in which the pump strokes draw a blood volume for the first duration into the blood inlet of the second pump station from the source and expel a blood volume for the second duration from the blood outlet of the first pump station to the filter, wherein the first duration is

longer than the second duration. A control function operates to synchronize the pump strokes so that blood flow from the source is essentially continuous while blood flow to the filter is pulsatile.

Specifically, for the reasons described above, which are incorporated by reference herein, neither the Kamen or Lundback patents disclose (1) pump strokes that draw a blood volume for a first duration into a blood inlet of a respective first and second pump station and expel a blood volume for a second duration from a blood outlet of a respective first and second pump station, and (2) wherein the first duration is longer than the second duration, and the Lundback patent also does not disclose various other features of the claimed system, as set forth in detail above. Further, Pages does not disclose any of the subject matter missing from either Kamen and/or Lundback, and is not properly combinable with Kamen and/or Lundback to achieve the claimed system.

More specifically, in contrast to the claimed system, Pages discloses a fluid circuit including a peristaltic pump 132 that operates on tubing line 130 to move fluid throughout the system, or similarly, a pair of peristaltic pumps 232a and 232b that operate on tubing line 230. See Pages, col. 3, lines 45-50 and Figure 1 and col. 6, lines 19-22 and Figure 2. There is simply no disclosure of a fluid pressure actuator, or first and second fluid pressure actuated pump stations and draw and pump durations, as presently claimed.

Further, Pages does not describe a fluid pressure actuator that includes a control function to switch between a first flow mode and a second flow mode as presently claimed. While Pages describes a draw cycle in which whole blood drawn from a donor

is centrifuged into its components and passed through a filter, and also describes operating the cycle a second time, if necessary, to process a particular volume of blood or components, each of these cycles operates fully and independently from one another. See col. 8, lines 19-25 of Pages which describes that “when the centrifuge bowl 210 is emptied or the predetermined volume of product processed, apparatus 200 begins a second draw cycle identical to that [first cycle] described above.” Thus, only when a “first” draw cycle is complete can the “second” cycle begin. No matter how the system in Pages is programmed or what processing procedure is intended to be performed, Pages does not describe a fluid pressure actuator including a control function as presently claimed, nor is Pages even capable of switching between a first flow mode and a second flow mode.

Further, Pages does not describe the claimed structure or its operation in which, in a first flow mode, pump strokes draw a fluid (blood) volume for a first duration into the fluid inlet of a first pump station from a source and expel a fluid (blood) volume for a second duration from the fluid outlet of the second pump station to a destination (or to a filter as recited in claim 13), and a second flow mode, in which the pump strokes draw a fluid (blood) volume for the first duration into the fluid inlet of a second pump station from a source and expel a fluid (blood) volume for the second duration from a blood outlet of a first pump station to a destination (or to a filter as recited in claim 13) wherein the first duration is longer than the second duration. Pages also does not describe a control function operating to synchronize pump strokes so that fluid flow from a source



is essentially continuous while fluid flow to a destination is pulsatile, as acknowledged by the Office in the Office Action dated August 18, 2008.

Instead, Pages describes a system with a peristaltic pump having a constant pumping rate, resulting in constant fluid flow. As it rotates, the peristaltic pump(s) 232a and 232b simply move fluid through the system at a constant target flow rate and constant target pressure. See Pages, col. 4, lines 23-34. Thus, Pages does not disclose or even contemplate pump strokes that draw a fluid (or blood) volume for a first duration and a expel a fluid (blood) volume for a second duration from respective first and second pump stations, wherein the first duration is longer than the second duration, as presently claimed

Thus, even if one were to combine Pages with the dialysis system of Kamen and/or the Lundback pump, the result would still not have the features of the claimed system. Accordingly, for at least the reasons stated above, Applicants submit that the pending claims would not have been obvious in view of the cited references, and the withdrawal of the rejections and reconsideration and allowance of the claims are respectfully requested.

The dependent claims 2, 3, 6, 8, 9, 12 and 14-18 recite additional features of the claimed system, and are dependent on amended independent claims 1, 7 and 13, respectively. For the reasons discussed above, it is respectfully submitted that the dependent claims also would not have been obvious in view of the cited references.

Clarification of Priority Claim

Finally, Applicants wish to bring the Examiner's attention to the clarification of priority claim that was submitted in response to the Office Action of June 14, 2007, filed on November 14, 2007. Specifically, the original claimed priority was to U.S. application Serial No. 9/390,265 filed September 3, 1999 and to U.S. application Serial No. 09/390,268 filed September 3, 1999. As pointed out in the amendment, this application is a division of the '265 application, which has issued as Patent No. 6,723,062. The claim of priority to the '268 application is deleted as unnecessary. However, to date, the USPTO records do not reflect this updated priority claim. Applicants therefore request that the Office acknowledge this priority claim and update the record accordingly.

Respectfully submitted,

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